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EXAMINER	
HADDAD, MAHER M	

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1644	

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Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary	Application No.	Applicant(s)	
	09/980,403	GULLBERG, DONALD	
	Examiner	Art Unit	
	Maher M. Haddad	1644	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE *3* MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *07 January 2008*.

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *26 and 156-162* is/are pending in the application.

4a) Of the above claim(s) *26* is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *156-162* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO/SB/08) Paper No(s)/Mail Date _____.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____.
5) ☐ Notice of Informal Patent Application
6) ☐ Other: _____.

DETAILED ACTION

1. Claims 26, 156-162 are pending.

2. Claims 26 are withdrawn from further consideration pursuant to 37 CFR 1.142(b), as being drawn to a nonelected invention.

3. Claims 156-162 are under examination as they read on a recombinant or isolated integrin subunit α11 having the amino acid sequence encoded by SEQ ID NO: 1.

4. Applicant's declarations and arguments submitted 1/17/08 are moot in view of the new ground of rejections. While both declarations and the remarks appear to argue that the αmt cloning from the G6 muscle cells using recombinant techniques known in the art at the time the invention was made, failed, however, the Examiner notes that the claimed domains and fragments can be obtained in an alternative enzymatic technique which would not require the use of recombinant methods.

5. The following new ground of rejections.

6. The following is a quotation of the second paragraph of 35 U.S.C. 112.

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

7. Claims 156-162 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

A. The recitation "comprising amino acid" in claims 156, 159, 160 is ambiguous. Given that the recited amino acid ranges are the claimed domains, it is not clear what is encompassing by the term "comprising". Do the claimed domains read on the full length of SEQ ID NO: 2 minus one amino acid? Or only on the claimed amino acid ranges? If it reads on the claimed ranges, then the claims should recite "consisting of". Given the ambiguity of the claimed domains it follows that the claimed fragments of claims 157-158 are ambiguous as well. If the term "comprising" is intended for the addition of heterologous sequence, it is suggested that the claims be amended to specifically indicate that. For example "a polypeptide comprising the extracellular domain of integrin subunit α11, wherein the extracellular domain of integrin subunit α11 consisting of amino acids 23-1141 of SEQ ID NO:2."

8. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless --

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

9. Claims 156-162 are rejected under 35 U.S.C. 102(b) as being anticipated by Gullberg *et al* (Dev. Dyn. 204:57-65, 1995) (IDS Ref. No. C2), as is evidenced by Velling *et al* (IDS Ref. No. C5).

Gullberg *et al* teach an isolated integrin subunit αmt obtained from G6 myoblasts and myotubes. Gullberg *et al* teach that αmt is induced upon myogenic differentiation (see abstract). Gullber et al teaches that under non-reducing conditions β1 associated protein migrated as 145 kD, wherein under reducing conditions, β1 integrin associated protein migrated in SDS-PAGE as a 155 kD protein (see abstract in particular). Gullberg *et al* teach that αmtβ1 heterodimer (see page 60, 2nd col., 2nd ¶ in particular). While the Gullberg *et al* teachings may be silent as to the "SEQ ID NO: 2" per se; the product is the same as the claimed product. As is evidenced by Velling *et al* that α11 is identical with αmt (see page 25740, 2nd col., end of the 1st ¶ in particular). Therefore "SEQ ID NO:2" is considered inherent properties.

Gullberg et al teach that the changes in the integrin levels were analyzed by immunoprecipitation with anti-β1 integrin IgG (a hetrodimer αmtβ1) of surface iodinated and metabolically labeled cultures followed by SDS-PAGE and autoradiography (see Fig.1 in particular).

It is noted that the processing of the signal peptide occurs in the trans-Golgi network. Accordingly, Gullberg's et al αmt on the SDS-PAGE and immunoprecipitation is a fragment of SEQ ID NO: 2 comprising the claimed domains. The referenced αmt is the full length minus the signal peptide. αmt reads on the claimed domains/fragments because the term "comprising" would open up the claimed domains/fragments to include the full length αmt minus the signal peptide.

Since the office does not have a laboratory to test the reference αmt, it is applicant's burden to show that the reference αmt is not α11 recited in the claim. See In re Best, 195 USPQ 430, 433 (CCPA 1977); In re Marosi, 218 USPQ 289, 292-293 (Fed. Cir. 1983); and In re Fitzgerald et al., 205 USPQ 594 (CCPA 1980).

The reference teachings anticipate the claimed invention.

10. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

11. Claim 156-162 rejected under 35 U.S.C. 103(a) as being unpatentable over Gullberg *et al*

(Dev. Dyn. 204:57-65, 1995) (IDS Ref. No. C2), as is evidenced by Velling *et al* (IDS Ref. No. C5), in view of in view of US. 5,304,603, US. 5,726,290, 6,030,947 and/or 5,968,770 patent.

Gullberg *et al* teach an isolated integrin subunit αmt obtained from G6 myoblasts and myotubes. Gullberg *et al* teach that αmt is induced upon myogenic differentiation (see abstract). Gullber et al teaches that under non-reducing conditions β1 associated protein migrated as 145 kD, wherein under reducing conditions, β1 integrin associated protein migrated in SDS-PAGE as a 155 kD protein (see abstract in particular). Gullberg *et al* teach that αmtβ1 heterodimer (see page 60, 2nd col., 2nd ¶ in particular). While the Gullberg *et al* teachings may be silent as to the "SEQ ID NO: 2" per se; the product is the same as the claimed product. As is evidenced by Velling *et al* that α11 is identical with αmt (see page 25740, 2nd col., end of the 1st ¶ in particular). Therefore "SEQ ID NO:2" is considered inherent properties. Gullberg et al teach that the changes in the integrin levels were analyzed by immunoprecipitation with anti-βl integrin IgG (a hetrodimer αmtβ1) of surface iodinated and metabolically labeled cultures followed by SDS-PAGE and autoradiography (see Fig.1 in particular).

The claimed invention differs from the reference teachings only by the recitation of the extracellular domain of integrin subunit α11 comprising amino acids 23-1141 of SEQ ID NO: 2 in claim 156, a fragment of the extracellular domain of integrin subunit α11 comprises the I-domain of integrin subunit α11 from amino acids 159 to 355 of SEQ ID NO: 2 in claim 157, or comprises amino acids 804 to 826 of SEQ ID NO: 2 in claim 158. The cytoplasmic domain of integrin subunit α11 comprising amino acids 1165 to 1188 of SEQ ID NO: 2 in claim 159 or the transmembrane domain of integrin subunit α11 comprising amino acids 1142 to 1164 of SEQ ID NO:2 in claim 160 and the heterodimer recited in claims 161 and 162.

The `603 patent teaches that one of the major goals of performing N-terminal sequence analysis is to define the identity of the purified protein following its comparison with existing protein and gene database. N-terminal sequence analysis will be performed on peptide fragments following tryptic/protease V8/CNBr fragmentation (the size of the fragments can vary depending on the enzyme used for digestion) to yield enough sequence information for preparation of antibodies against peptide fragments and to prepare oligonucleotides for gene cloning experiments. The peptide fragments will either be separated by SDS-PAGE, transferred onto PVDF membrane and sequenced, or by C18 reversed-phase HPLC. The former procedure will be useful to generate sufficient sequence data for subsequent studies if the protein of interest cannot be purified to apparent homogeneity, whereas the latter procedure will be the technique of choice since about 30-50 PTH(phenylthiohydantoin)-amino acids can be determined in a single sequence experiment (see col., 8 line 47-68 in particular).

The `290 patent teaches that the boundary for a multiple subunit polypeptide (MSP) extracellular domain generally is at, or within about 20 residues N-terminal form, the N-terminus of the membrane anchor domain, and are readily identified from an inspection of the MSP sequence. It is not necessary to use the entire MSP extracellular domain, however, since smaller segments are commonly found to be adequate for ligand binding. Such segments are routinely identified by

making deletional mutants or enzymatic digests (the size of the fragments can vary depending on the enzyme used for digestion) and screening for ligand binding to identify active fragments (see col., 8 line 26-35 in particular).

The `947 patent teaches that any of a variety of methods may be used to clone the p150,95 alpha-subunit gene. One such method entails analyzing a shuttle vector library of cDNA inserts (derived from a p150,95 alpha-subunit expressing cell) for the presence of an insert which contains the p150,95 alpha-subunit gene. Such an analysis may be conducted by transfecting cells with the vector, and then assaying for p150,95 alpha-subunit expression. A preferred method for cloning the p150,95 alpha-subunit gene entails determining the amino acid sequence of the p150,95 alpha-subunit molecule. To accomplish this task, p150,95 alpha-subunit molecules are preferably purified from producer cells by monoclonal antibody affinity chromatography and isolated by preparative sodium dodecyl sulfate-polyacrylamide gel electrophoresis ("SDS-PAGE") and electroelution. The alpha-subunit molecules are fragmented as with cyanogen bromide, or with proteases (the size of the fragments can vary depending on the enzyme used for digestion) such as papain, chymotrypsin, or trypsin. Preferably, the alpha-subunit is proteolytically digested with trypsin. The resulting peptides are separated by reverse-phase HPLC and subjected to amino acid sequencing. To accomplish this task, the protein is, preferably, analyzed by automated sequenators. Although it is possible to determine the entire amino acid sequence of the p150,95 alpha-subunit, it is preferable to determine the sequence of peptide fragments of the molecule (see col., 5 under section II in particular).

The `770 patent teaches that techniques can be employed using peptide fragments that correspond to the binding domains of the target gene protein and the interactive cellular or extracellular protein, respectively, in place of one or both of the full length proteins. Any number of methods routinely practiced in the art can be used to identify and isolate the protein's binding site. These methods include, but are not limited to, mutagenesis of one of the genes encoding the proteins and screening for disruption of binding in a co-immunoprecipitation assay. Compensating mutation in the target gene can be selected. Sequence analysis of thegenes encoding the respective proteins will reveal the mutations that correspond to the region of the protein involved in interactive binding. Alternatively, one protein can be anchored to a sold surface and allowed to interact with and bind to its labeled binding partner, which has been treated with a proteolytic enzyme (the size of the fragments can vary depending on the enzyme used for digestion) such as trypsin. After washing, a short, labeled peptide comprising the binding domain may remain associated with the solid material, which can be isolated and identified by amino acid sequencing. (see col., 40, lines 40-61 in particular).

It would have been obvious to one of ordinary skill in the art at the time the invention was made to enzymatic digest αmt subunit taught by Gullberg *et al* using the techniques taught by the `603, `290, `947, `770 patent. The resultant fragments would comprise the claimed domains.

One of ordinary skill in the art at the time the invention was made would have been motivated to do so because to 1) prepare antibodies against peptide fragments and to prepare oligonucleotides for gene cloning experiments as taught by `603 patent, 2) identify active fragments in ligand

binding as taught by the `290 patent, 3) clone αmt subunit as taught by the `947 patent, or 4) identify and isolate the αmt's binding site as taught by `770 patent.

From the combined teachings of the references, it is apparent that one of ordinary skill in the art would have had a reasonable expectation of success in producing the claimed invention. Therefore, the invention as a whole was *prima facie* obvious to one of ordinary skill in the art at the time the invention was made, as evidenced by the references, especially in the absence of evidence to the contrary.

Given the examination guidelines for determining obviousness under 35 U.S.C. 103 in view of the Supreme Court decision in *KSR International Co. v. Teleflex Inc.* 82 USPQ2d 1385 (2007) and the Examination Guidelines set forth in the Federal Register (Vol. 72, No. 195, October 10, 2007) and incorporated recently into the MPEP (Revision 6, September 2007), the following rationales to support rejection under 35 U.S.C. 103(a) are noted:

A) Combining prior art elements according to known methods to yield predictable results.

The rationale to support a conclusion that the claims would have been obvious is that all the claimed elements (αmt) were known in the prior art and one skilled in the art could have arrived at the claimed invention by using known methods (enzymatic digestion) with no change in their respective functions and the combination would have yielded nothing more than predictable results of peptide fragments/domains of αmt.

B) Use of known technique to improve similar products in the same way.

The rationale to support a conclusion that the claims would have been obvious is that a method of enzymatically digesting a protein of interest was made part of ordinary capabilities of one skilled in the art based upon the teachings of the patents. One of ordinary skill in the art would have been capable of applying the known methods of digesting the protein of interest with an enzyme to obtain peptides/fragments/domains and the results would have been predictable to one of ordinary skill in the art.

C) Applying a known technique to a known product ready for improvement to yield predictable results.

The rationale to support a conclusion that the claims would have been obvious is that a particular known technique (enzymatic digestion) was recognized as part of the ordinary capabilities of one skilled in the art. One of ordinary skill in the art would have been capable of applying this known technique to a known product (e.g. αmt) that was ready for improvement and the results would have been predictable to one of ordinary skill in the art.

D) "Obvious to try" --- choosing from a finite number of identified, predictable solutions, with a reasonable expectation of success.

The rationale to support a conclusion that the claim would have been obvious is that a person of ordinary skill has good reason to pursue the known options (e.g. enzymatic digestion of a protein of interest) within his or her technical grasp. This leads to the anticipated success of obtaining the claimed domains/fragments, it is likely the product not of innovation but of ordinary skill and common sense.

E) Some teachings, suggestion, or motivation in the prior art that would have lead one of ordinary skill to modify the prior art reference to arrive at the claimed invention.

Since Gullberg et al identify domains and fragments of a novel integrin α-chain (αmt) on human fetal myotubes, which is induced upon myogenic differentiation and important for myogenesis during different developmental stages would have been predictable at the time of the invention, there would have been reasonable expectation of successful preparing domains/fragments of αmt as claimed. The prior art had recognized the alternative techniques produce protein fragments/domains, and had suggested both recombinant and non-recombinant (enzymatic) methods to overcome this obstacles. The claims were obvious because it would have been obvious to try the known methods of enzymatic digestion of the novel αmt, with a reasonable expectation of success.

In this case, the αmt chain was taught by Gullberg et al provides a point of intervention for obtaining the α-chain domains that are responsible for the myogenic differentiation. A person of ordinary skill has good reason to pursue the known options, e.g. enzymatic digestion of αmt, within his or her technical grasp with reasonable expectation of success.

"The test of obviousness is not express suggestion of the claimed invention in any or all of the references but rather what the references taken collectively would suggest to those of ordinary skill in the art presumed to be familiar with them." See *In re Rosselet*, 146 USPQ 183, 186 (CCPA 1965).

"There is no requirement (under 35 USC 103(a)) that the prior art contain an express suggestion to combine known elements to achieve the claimed invention. Rather, the suggestion to combine may come from the prior art, as filtered through the knowledge of one skilled in the art." *Motorola, Inc. v. Interdigital Tech. Corp.*, 43 USPQ2d 1481, 1489 (Fed. Cir. 1997).

An obviousness determination is not the result of a rigid formula disassociated from the consideration of the facts of a case. Indeed, the common sense of those skilled in the art demonstrates why some combinations would have been obvious where others would not. See *KSR Int'l Co. v. Teleflex Inc.*, 82 USPQ2d 1385 (U.S. 2007) ("The combination of familiar elements according to known methods is likely to be obvious when it does no more than yield predictable results.").

Given that the prior art alternative method of obtaining protein's domains/fragments/peptides would have been routine to the ordinary artisan at the time the invention was made and therefore obvious in preparing a domain/fragment of αmt as claimed.

In conclusion, given that the prior art teaches the use of enzymatic digestion to obtain domains/fragments/peptides, the prior art also provides multiple working examples of obtaining domains/fragments/peptides using enzymatic digestion, it would have been obvious to one of skill in the art at the time of the invention to achieve the predictable results of obtaining the claimed domains/fragments. The term "comprising" would open up the claimed domains/fragments to any resultant fragment that comprising the claimed domain/fragment. Since it is well known that the size of the fragments can vary depending on the enzyme used for digestion, the skilled in the art can chose the specific enzyme need.

Applicant's arguments, filed 1/17/08, have been fully considered, but have not been found convincing.

Regarding Applicant argument that Gullberg et al did not isolate specific and identifiable new molecule of αmt, the Examiner would like to draw Applicant's attention to Wier et al (Handbook of Experimental immunology Volume 1: Immunochemistry, 1986, pages 8.14-8.15). Wier et al teach that single bands can be cut from polyacrylamide gels (PAGE), the protein electro-eluted for immunization, in FCA or alternatively the antigen and gel can be frozen and thawed to break up the gel and the whole mixture emulsified in FCA ready for injection s.c. or i.m. The acrylamide gel seems to have adjuvant properties and high antibody titres have been obtained in rabbits immunized in this way. Accordingly, the αmt band is considered as isolated specific and identifiable.

In view of the new rejection, the arguments that are based on the technical problems (recombinant technique) on how to apply the teachings of Alberts et al to the integrin αmt or integrin α11 are moot.

Regarding the issue that the integrin αmt of Gullberg et al is a biochemcial entity that was characterized exclusively by immunological methods, it remains the examiner's position that αmt is α11. Further, the Examiner shifts the burden to applicant to show that the referenced αmt is not the claimed α11. It is noted that the specification (page 19, under cDNA clonign of a novel integrin α-chain) discloses that integrin sequences obtained in subtractive hybridization protocol can be amplified by PCR from human fetal G6 myoblast cDNA, PCR was performed assuming that these sequence were derived from the same transcript. In this manner a 1.4 kb cDNA fragment with integrin like sequence was obtained. Screening of a human fetal myoblast cDNA library and`5` RACE yielded additional 5` sequence. The complete open reading frame was identified using uterus cDNA.

Regarding Applicant arguments that Gullberg et al merely identified a biochemical entity whose sequence identity, structure, and relation to other molecules, including some of the integrin a chains, remained undefined. It remains the Examiner's position that disclosure of SEQ ID NO: 2 is only further characterization of otherwise old product. Mere recognition of the amino acid

sequence of αmt of Gullberg does not render nonobvious an otherwise known invention. The Examiner places the burden on applicant to distinguish his α11 from the prior art αmt.

Applicant argues that it was well established at the time that integrins are a very complex family of proteins, in part, due to alternative splicing. It remains the Examiner's position that Applicant burden to show that the αmt is not α11. Applicant does not provide objective evidence to distinguish the αmt of Gullberg et al from the claimed α11. Further, Gullberg et al, on page 61, top ¶ teach that a weak 95Kd band in metabolically labelled cultures, indicating a low level of α7 expression in G6 cells.

Applicant submits that no definitive evidence was provided for this proposition (αmt is identical to αll). Contrary to Applicant assertions, the specification on page 25, lines 35-37 discloses that the "α11 integrin is identical with αmt". Further, the rejection cited Velling et al as evidence that "α11 is identical with αmt" (see page 25740, 2nd col., end of the 1st ¶ in particular).

Regarding Applicant arguments that Applicant was never able to succeed in cloning an integrin α11 cDNA from a G6 cell cDNA library, arguing against a sequence identity between integrin αmt and integrin α11. However, Applicant's own specification on page 16, under screening of cDNA libraries discloses the use of G6 cDNA library was screened PCR2 probe resulted in two clones representing the 5` non-coding region and the beginning of the coding part of integrin α11. This provide evidence for sequence identity between integrin αmt and integrin α11, specially because the same probes were used to fish out the gene of interest from a uterus cDNA library.

Applicant argues that Gullberg et al did not provide any guidance on the methods for separating integrin αmt from the other estimated 9,999 proteins in the cell. Contrary to Applicant assertion, Gullberg separated the αmt from the other estimated 9,999 proteins in the cells using SDS-PAGE (see Fig 1 of Gullberg). SDS-PAGE is used to separate proteins according to their electrophoretic mobility. Further, the Examiner notes that αmt was detected on the gel (fig. 1).

The reminder of the remarks and the declarations deal with the lack of reasonable expectation of success using the recombinant methodology. The arguments/declarations are moot in view of the new rejection that does not require recombinant techniques but enzymatic digestion of the αmt protein to arrive to the claimed invention.

12. No claim is allowed.

13. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Maher Haddad whose telephone number is (571) 272-0845. The examiner can normally be reached Monday through Friday from 7:30 am to 4:00 pm. A message may be left on the examiner's voice mail service. If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Eileen B. O'Hara can be reached on (571) 272-0878.

The fax number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

April 8, 2008

/Maher M. Haddad/
Primary Examiner,
Art Unit 1644